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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,934

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Bent Piil Pedersen

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EXAMINER

SAYALA, CHHAYA D

ART UNIT

PAPER NUMBER

1794

NOTIFICATION DATE

DELIVERY MODE

10/20/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

Office Action Summary	Application No. 10/524,934	Applicant(s) PEDERSEN ET AL.	
	Examiner C. SAYALA	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/14/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 3-7, 9, 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Feldman et al. (US Patent 3857966) taken in light of Loosen et al. (US Patent 5356637).

Feldman et al. teach the hydrolysis of fish protein by reacting the protein first with an alkaline protease and then with a neutral protease to obtain such benefits as protein that is soluble and bland so that it can be used in food substrates without adversely affecting their clarity and consistency of texture. See col. 2, line 8, Example III.

The protein is inactivated after completion of the reaction by raising the temperature. See col. 4, lines 48-54, col. 1, lines 58-65.

Both the enzymes are obtained preferably from *Bacillus*. See col. 3, lines 48-51 and col. 4, lines 11-30. Note that the patent teaches “Alcalase” as the alkaline protease which was known to be derived from *Bacillus licheniformis*, at the time the invention was made. See Loosen et al. at col. 4, lines 34-35 cited here as an evidentiary reference to this fact.

With regard to claim 14, the protein is centrifuged after hydrolysis, to separate the solids. With regard to claim 15, use of a centrifuge meets the necessary

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“separator”. With regard to drying the product, the patent teaches freeze-drying. Col. 2, lines 32-34, 50-55, 63-68; col. 5, lines 8-11, Example III.

With regard to claims 3-6, these claims describe the various animals the feed is intended for, which is deemed as “use terminology”. The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, cannot impart patentability to claims to the known composition. *In re Spada*, 15 USPQ 2d, 1655.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 2, 10, 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman et al. in view of Faith Jr. et al. (US Patent 3697285).

Feldman is as described above. Feldman does not teach the removal of oil or that the fish is raw.

The Faith reference teaches the hydrolysis of fish proteins and teaches that after the enzymatic hydrolysis, the resulting slurry of protein solution, oil and solids is then separated into its components by filtering and then centrifuging. The solution is then dried by spray or air or *drum-drying* to obtain a soluble fish protein. See col. 3, line 74

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to col. 5, line 6. Note example 1, which teaches hydrolyzing raw fish. To start the hydrolysis using Feldman's disclosure and raw fish would not require more than ordinary skill with the reasonable expectation in that a soluble bland fish protein would result.

3. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman et al. in view of Freeman et al. (US Patent 4473589) and Weeks et al. (US Patent 3578461).

Feldman is discussed above. The reference does not disclose that the protein hydrolyzate is used in a method to feed animals. Freeman teaches the use of a hydrolyzed fish protein as feed supplements. See col. 1, line 17, col. 2, line 8. Weeks teaches that hydrolyzed protein "can serve as a highly nutritious source of protein for animals." Such disclosures render obvious feeding animals with hydrolyzed proteins.

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over feldman et al. in view of Weeks et al., Ikeda et al. (US Patent 4036993) and FR 2352498.

Feldman is as discussed above. Feldman does not show that the fish meat was not heated above 70⁰C before hydrolysis. Weeks teaches heating to 37⁰C, (Example 1). Ikeda teaches elevating the temperature to above 60⁰C, which would include the range 60-70⁰C. Freeman teaches a temperature range 120-170⁰F, which includes a temperature of about 76⁰C at its highest. FR '498 teaches heating fish to 40⁰C before

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being subjected to enzymatic action. What such temperatures show is that while temperatures below 70°C were in fact in use at the time the invention was made for the same purpose, the ranges shown render obvious that determining such temperatures are within the ambit of routine skill based on the enzyme used, the type of protein and hydrolysis required.

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman et al. in view of Xu et al. (US Pub. 2002/0004085).

Feldman is as discussed above with respect to claim 1. Feldman does not disclose that the neutral protease is obtained from *Bacillus amyloliquefaceins*. See ¶ [0081] in Xu et al. that teaches GLUTENASE or NEUTRASE as enzymes that are neutral proteases obtained from *Bacillus amyloliquefaceins*. To use such enzymes as the neutral protease of Feldman et al. would have been prima facie obvious.

6. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman et al. in view of Feldman et al. in view of Blinkovsky et al. (US Patent 6187578) and Olsen (US Patent 4324805).

Feldman is as described above. Note that claim 1 is written in a product-by-process format and the patentability of a product is not dependent on its method of production. Claims 12 and 13 recite the degree of hydrolysis to which the fish meat is hydrolyzed. Feldman does not disclose this feature.

Blinkovsky teaches the following @ col. 1, lines 39-47 and col. 2, lines 16-23:

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Enzymatic hydrolysis processes aim at obtaining a high degree of hydrolysis (DH), and this is usually attained using a complex of unspecific acting proteolytic enzymes (i.e., unspecific acting endo- and exo-peptidases). For example, WO 94/25580 describes a method for hydrolyzing proteins by use of an unspecific acting enzyme preparation obtained from *Aspergillus oryzae*. Specific acting proteolytic enzymes have not been used for this purpose because such enzymes only lead to an inadequate degree of hydrolysis.

The production of protein hydrolysates with desirable organoleptic properties and high degrees of hydrolysis generally requires the use of a mixture of peptidase activities. It would be desirable to provide a single component peptidase enzyme which has activity useful for improving the organoleptic properties and degree of hydrolysis of protein hydrolysates used in food products either alone or in combination with other enzymes.

Olsen discloses @ col. 3, line 48 to col. 4, line 9:

The degree of hydrolysis (DH) is defined by the equation:
$$\text{DH} = \frac{\text{Number of peptide bonds cleaved}}{\text{Total number of peptide bonds}} \times 100\%$$

Reference is made to J. Adler-Nissen, J. Agric. Food Chem., Vol. 24, No. 6, (1976) page 1090-1093 where a more detailed discussion of the definition of DH appears.

The number of the peptide bonds cleaved can be measured by means of the ninhydrin method. The ninhydrin method is described in Moore, S., Stein, W. H., "Photometric Ninhydrin Method for use in the Chromatography of Amino Acids", J. Biol. Chem., 176, 367-388 (1948).

The DH can also be determined if the course of hydrolysis is followed by means of the pH-STAT method, as described in Jacobsen, S. F., Leonis, J. Linderstrom-Lang, K., Ottesen, M., "the pH-STAT and its use in Biochemistry", in Glick, D., (edit.), "Methods of Biochemical Analysis", Vol. IV, pp. 171-210, Interscience, Publishers Inc., New York (1957).

As is apparent from the above the DH plays an important role in the invention, inasmuch as the hydrolysis is controlled by means of the DH; only when DH has reached a critical value, the

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hydrolysis may be terminated. The DH is, so to speak, the main parameter of the hydrolysis.

Based on these teaching references it would have been obvious to select the enzymes as in Feldman and as taught by these references, it would have been obvious to aim at obtaining a high degree of hydrolysis. It would have also been obvious to follow the course of the hydrolysis to determine the DH, to measure the peptide bonds cleaved (by the ninhydrin method) and to calculate and control the degree of hydrolysis and to terminate the hydrolysis when the desired DH is reached. Therefore, the DH claimed would have been determinable and controlled to the extent required by the artisan, and given the teachings of the secondary references, this would have been within the ambit of the routineer.

Claim Rejections - 35 USC § 102/ Claim Rejections - 35 USC § 103

7. Claims 12 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Feldman et al.

Claims 12 and 13 depend from claim 1 which has been written in a product-by-process format and as such it is the novelty of the product that needs to be established and not that of the process steps. The degree of hydrolysis is not described by Feldman et al. However, applicant has chosen to describe his product with characteristics that cannot be measured by the Office, and that burden is being shifted to applicant. Furthermore, it is well established that "[E]ven though product-by-process

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claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious over a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The art not applied but cited shows that for hydrolyzing fish, a combination of the same enzymes were useful and already being practiced.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Sayala whose telephone number is (571) 272-1405. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business

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Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. SAYALA/

Primary Examiner, Art Unit 1794